CORPORATION

SYSTEM SERVICE TEST METHOD

For use with:

COOLGARD 3000 w/ EPS and Thermogard systems

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1 OBJECTIVE

The objective of this test method is to verify that the CG3000 system has been properly serviced and functions as required. This test method is to be applied after each service of the CG3000 system.

2 MATERIAL USED

- Air Trap Test Fixture P/N 300954
- 2-FOGG Temperature Simulators TP400 with Alsius adapters
- Laptop Computer loaded with Alsius TempTrend software
- 50/50 mix propylene glycol/distilled water P/N 400333-001
- RS-232 Serial Cable
- Stop Watch

3 PROCEDURES

3.1 Power up Self Test

- Fill coldwell with 50/50 propylene glycol/ distilled water mix to **MAX** level mark inside the coldwell.
- Turn on the system.
- On the display, observe that the red LED blinks three times and the alarm beeps three times at power up.
- Verify that the software version is 2.0 or higher. If it is 1.05 or lower, you must use TM-031 SYSTEM FUNCTIONAL TEST METHOD.
- **Record software version.**
- Verify green LED's on display and back panel are lit.
- Check coolant level and fill coolant back up to **MAX** level if necessary.

3.2 System Set-up: Follow the screen prompts as follows:

- System may display "**Coolant Low**". It may take up to 5 minutes for coolant level to be detected.
- **System Pre-set** ⇒ Select **Pre-warm** and press **Enter**.
- **Operate at Current Settings** ⇒ Select **No** and press **Enter**. (If an "Operate at current settings" screen is not displayed, skip to next step.)
- **New Patient** ⇒ Select **No** and press **Enter** (If a "New Patient" screen is not displayed, skip to next step.)
- **Target Temperature** ⇒ Set the target temperature to **36.5 °C** and press **Enter**.
- **Select Treatment Mode** ⇒ Select **Max Power** and press **Enter**.
- Wait until the self test is complete.
- Observe "Check The Following" screen. All fields should be Blue, except **"Air Trap"**

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- Open and close the pump door and verify the change in color from Blue to Red and back to Blue of **"Roller Pump Lid".**
- Press and hold the prime switch, verify the change in color from Blue to Red of **"Check Prime Switch".**
- Release the prime switch. Verify the change in color of **"Check Prime Switch"** back to Blue.
- Fill Air Trap fixture with saline or water.
- Place filled Air Trap fixture into system air trap holder.
- Observe **"Air Trap**" change from Red to Blue. The system will then automatically go into the **STANDBY** mode.

3.3 Time & Date set-up

- Enter Settings menu and adjust the time & date to the local time.

3.4 Temperature Input check

Set TP-400 to **37.0°C** and connect to T1. Record **Patient Temp** displayed on screen.

3.5 Run Mode Verification

- Adjust TP-400 setting to 36.0ºC. Leave connected to T1.
- Set second TP-400 to 36.0ºC and connect to T2.
- Press the Standby/Run button.
- Verify that the word STANDBY immediately disappears from the screen and the system goes into the **RUN** mode.
- Remove the TP-400 that is connected to T2. Do **not** remove the TP-400 connected to T1.
- System should alarm audibly and display alarm message **"Secondary temp probe (T2) disconnected …"**
- Press the Enter knob. Audible alarm should stop and message should disappear. System should automatically be in **STANDBY** mode.
- With a TP-400 still set to 36.0ºC and connected to T1, press the **Standby/Run button**.
- A full screen yellow message box will appear ⇒ Select **YES**.
- Verify that the yellow message screen disappears and the system goes into **RUN** mode.
- Confirm that the roller pump begins turning **counter clockwise** and reaches full speed within approximately 30 seconds. (If the roller pump does not begin turning immediately, leave the system in RUN until it does start turning.)
- Verify that **coolant is circulating** within the coldwell.
- Verify that the **blower fan** is operating.
- Verify that the **Target Temp** displayed on the screen is **36.5°C**.
- Verify that the **Rate** displayed on the screen is **MAX.**

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3.6 Pump Door and Mute Button Test

- Open pump lid. Observe system audibly alarming, with message **"Pump Door Open"** and system goes to "Standby" mode.
- Press **Mute** button. Alarm should silence.
- Press **Enter** to clear alarm and close pump lid.
- Verify that alarm message disappears.
- Place system back into **RUN** mode.

3.7 Air Trap Test

- Set unit in **STANDBY** mode.
- Remove Air Trap fixture from system.
- Verify that the message **"AIR TRAP FAULT – Check Saline Level"** is displayed on screen.
- Replace Air Trap fixture in system and wait for the message to clear.

3.8 Target Temp Set-up

- Press **Target Temp** button.
- Rotate dial to **38.0°C** and press **Enter**.
- Verify that Target Temp on screen is **38.0°C**.

3.9 Rate Set-up

- With the system in **STANDBY**, press the **Rate Deg/Hr** button
- Rotate the menu knob and verify that the following rates are displayed: **Max Power / Controlled Rate / Fever.**
- Select the **Controlled Rate Mode** and rotate knob. Verify that the rate selection changes from 0.10 to 0.65 ºC/Hr. Select any rate by pressing knob.
- Press **Rate Deg/Hr** button again and change the Rate back to **MAX**.

3.10 Verify Slew Rate

- Confirm that the Target Temperature is set to **38.0°C** and that the Rate is set to **MAX.**
- Set TP-400 in T1 to **36.0°C**.
- Place system in **RUN** mode.
- Allow bath to reach high rail and stay there for at least 5 minutes.
- Set Target Temperature to **35.0°C**.
- Place system back in **RUN** mode.
- Wait for coolant bath to reach the very bottom rail for at least 3 minutes.
- Press knob and **select View Graphs**.
- Rotate the knob slowly until the CoolGard value displayed in the box at the bottom of the graph first changes from MAX in red to MED in red. Leave it in the **MED** red position (see example below).
- **Record the time** displayed at top of graph.

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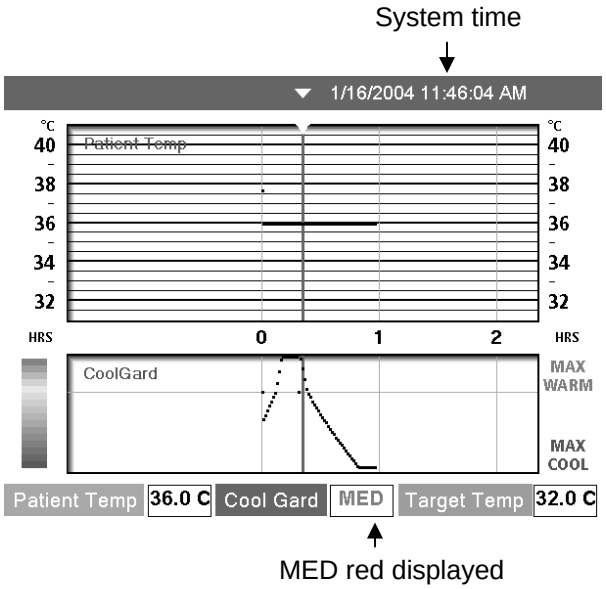
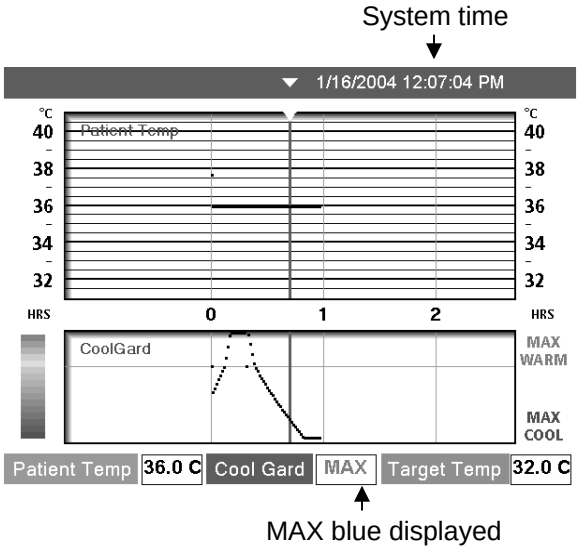


- Rotate the knob again until the CoolGard value displayed in the box just changes from Blue MED to Blue MAX. Leave it in the MAX position (see example below).
- **Record the time** displayed at the top of the graph.



- **Verify that the elapsed time between these two values is less than 30 minutes. Record the value.**

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3.11 Peristaltic Pump Test

- Place system in Standby mode; verify that the screw located in the center of the Pump Rotor assembly is fully tightened.
- Place system in Run mode, measure how many complete rotations the pump turns within a minute by using a stopwatch and a start point.
- Record how many rotations per minute; verify that it is between 35 and 43 cycles per minute.

3.12 Patient Data Download

- Perform a patient data download per TM-021.

4 DATA AND RESULTS

Verify that all data and results have been recorded on the System Service Test Record (Form 250).

5 ACCEPTANCE/ REJECT CRITERIA

See requirements listed on the System Service Test Record (Form 250).

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